UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

GLORIA GUIDRY	CIVIL ACTION
V.	NO. 15-4591
JANSSEN PHARMACEUTICALS, INC., ET AL.	SECTION "F"

ORDER AND REASONS

Before the Court are two motions to dismiss the plaintiff's amended complaint. The first motion is by two defendants the Court refers to as the Mitsubishi Defendants. The group includes Mitsubishi Tanabe Pharma Corporation (Mitsubishi Japan) and Mitsubishi Tanabe Pharma Development America, Inc. (Mitsubishi America). The second motion is by a group of defendants the Court refers to as the Janssen Defendants. This group includes: Janssen Pharmaceuticals, Inc.; Janssen Ortho, LLC; Janssen Research & Development, LLC; Johnson & Johnson Services, Inc.; and Johnson & Johnson. For the following reasons, the Mitsubishi Defendants' motion is GRANTED; the Janssen Defendants' motion is GRANTED IN PART and DENIED IN PART.

Background

This case is here for Round Two.

Gloria Guidry brings this products liability lawsuit after suffering acute kidney injury and acute kidney failure allegedly caused by taking Invokana, a prescription drug manufactured, licensed, and distributed by the defendants.

After Guidry filed her initial complaint, the defendants moved for dismissal under Federal Rule of Civil Procedure 12(b)(6). In its Order and Reasons dated February 17, 2016, the Court granted the defendants' motion and dismissed the plaintiff's complaint. The Court, however, allowed the plaintiff to amend her complaint and refile it within fourteen days. The plaintiff complied with the Court's Order. Now the defendants seek dismissal of her amended complaint.

Gloria Guidry's doctor prescribed Invokana to treat her Type II diabetes. She took Invokana from approximately March 11, 2014 until she was hospitalized for acute kidney injury and acute kidney failure on September 21, 2014. She remained hospitalized for a week. Guidry charges that the prescription drug caused her kidney failure.

Invokana is the first diabetes treatment to be approved in a new class of drugs known as sodium-glucose co-transporter 2 (SGLT2) inhibitors. Invokana is designed to help diabetics reduce excess blood sugar. It works by blocking reabsorption of glucose in the kidneys, and, instead, it increases glucose excretion through urination. Other diabetes drugs help the body reabsorb or metabolize blood sugar; Invokana is designed to help the body reduce blood sugar through urination.

According to the plaintiff, Invokana overworks the kidneys by forcing them to filter the excess blood sugar. Because Invokana

blocks the kidneys from reabsorbing the sugar, the kidneys push the excess blood sugar through the urinary tract instead. The plaintiff urges that this excess sugar builds up in the tubes connecting the kidneys to the bladder, forcing the kidneys to work harder than normal to function properly. The plaintiff maintains that this added stress causes kidney injury or failure.

The plaintiff contends that the defendants were aware of these adverse effects before Invokana was ever approved by the Food and Drug Administration. She points out that medical documents submitted with Invokana's New Drug Application disclosed a three-fold increase (1.7% compared to 0.6%) in acute renal (kidney) failure for patients taking a higher dose of Invokana compared to those taking a placebo. This was true even in patients with normal kidney function.

The plaintiff also submits that the defendants marketed and promoted Invokana for off-label purposes such as weight loss. She contends (somewhat vaguely) that she "became aware" of these promotional materials and formed the belief that Invokana was safe to treat her diabetes.[1] The plaintiff claims that the defendants' advertisements overstated Invokana's ability to reduce blood sugar

[1] The plaintiff claims that the added weight loss benefit was intended to boost the drug's appeal among Type II diabetics because, often, diabetics need to lose weight. She claims, however, that the supposed weight loss side-effect is merely a byproduct of the increased rate in urination. The plaintiff calls this "water weight," which returns when the person's fluids are corrected.

levels and failed to disclose the risks of severe kidney injury. She maintains that Invokana's risks substantially outweigh its benefits. Invokana reduces hemoglobin levels (i.e., blood sugar levels) by 0.62% for the 100 mg dosage and by 0.77% for the 300 mg dosage, both of which the plaintiff describes as a "very weak reduction."

The plaintiff claims that the defendants concealed their knowledge of the dangerous side effects of the medication and provided inadequate warnings to doctors and consumers. Had she known of the risks, the plaintiff maintains, she would not have taken Invokana. She also urges that the defendants failed to adequately complete testing of Invokana before filing for a New Drug Application with the FDA. She concludes that the defendants' negligent actions and omissions were a proximate cause of her acute kidney failure, a condition that has left her with permanent injuries.[2]

The plaintiff makes claims under the Louisiana Products Liability Act. She asserts five Invokana defects: 1) in composition or construction; 2) in design; 3) for failing to provide adequate warnings; 4) for breach of an express warranty; and 5) because it

[2] The plaintiff also repeatedly emphasizes the reported correlation between taking Invokana and developing ketoacidosis or diabetic ketoacidosis. However, she never claims explicitly that she suffers from either condition. Likewise, she underscores the alleged cardiovascular risks of taking Invokana, but she makes no mention of actually suffering cardiovascular maladies.

is either useless or so inconvenient that a knowing buyer would not have purchased it.

The Mitsubishi Defendants move to dismiss on three grounds. First, they challenge this Court's personal jurisdiction, invoking Federal Rule of Civil Procedure 12(b)(2). Second, they assert insufficient service of process under Rule 12(b)(5). Finally, they submit that the plaintiff has failed to plead facts sufficient to satisfy Rule 12(b)(6). They urge that the plaintiff's claims are preempted by federal law.

The Janssen Defendants also move to dismiss under Rule 12(b)(6). They contend that the plaintiff has failed to allege sufficient facts to satisfy federal pleading standards, and the plaintiff's state law claims are preempted by federal law. The Court addresses each motion separately.

I. The Mitsubishi Defendants

The Mitsubishi Defendants move to dismiss the plaintiff's complaint for lack of personal jurisdiction, insufficient service of process, and failure to state a claim. The Mitsubishi Defendants also incorporate by reference the arguments made by the Janssen Defendants. The Court first addresses the existence of its personal jurisdiction over the Mitsubishi Defendants. Finding it lacking, the Court does not consider Mitsubishi's remaining grounds for dismissal.

A.

"Federal courts ordinarily follow state law in determining the bounds of their jurisdiction over persons." Daimler AG v. Bauman, 134 S.Ct. 746, 753 (2014). However, "[t]he Due Process Clause of the Fourteenth Amendment sets the outer boundaries of a state tribunal's authority to proceed against a defendant." Goodyear Dunlop Tires Operations, S.A. v. Brown, 564 U.S. 915, 923 (2011). Louisiana's long-arm statute confers personal jurisdiction over out-of-state defendants who conduct a wide range of activities within the State. See La. R.S. § 13:3201. But because the State's authority to proceed against an out-of-state defendant is confined by the Fourteenth Amendment, the Court first addresses whether it may exercise personal jurisdiction over the defendants in a manner consistent with due process.

The "canonical opinion" governing personal jurisdiction remains International Shoe Co. v. Washington, 326 U.S. 310 (1945). See Daimler, 134 S.Ct. at 754. There, the Supreme Court held that "a State may authorize its courts to exercise personal jurisdiction over an out-of-state defendant if the defendant has 'certain minimum contacts with [the State] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.'" Goodyear, 564 U.S. 915, 923 (2011)(quoting International Shoe, 326 U.S. at 316). Within the International Shoe framework, two categories of personal jurisdiction exist:

specific jurisdiction and general jurisdiction. See id. Specific jurisdiction exists when a suit arises out of or relates to the defendant's contacts with the forum state. Daimler, 134 S.Ct. at 754; Helicopteros Nacionales de Colombia, S.A. v. Hall, 466 U.S. 408, 414 (1984). On the other hand, a court has general jurisdiction over a foreign corporation "to hear any and all claims against them when their affiliations with the State are so continuous and systematic as to render them essentially at home in the forum State." Daimler, 134 S.Ct. at 754 (quoting Goodyear, 564 U.S. at 919).

The plaintiff here does not contend that the Court has general jurisdiction over the Mitsubishi Defendants. She relies exclusively on specific jurisdiction.

The Fifth Circuit instructs, "Specific jurisdiction 'focuses on the relationship among the defendant, the forum, and the litigation.'" Monkton Ins. Services, Ltd. v. Ritter, 768 F.3d 429, 432-33 (5th Cir. 2014)(quoting Walden v. Fiore, 134 S.Ct. 1115, 1121 (2014)). "'For a State to exercise jurisdiction with due process, the defendant's suit-related conduct must create a substantial connection with the forum State.'" Id. (quoting Walden, 134 S.Ct. at 1121). This Circuit applies a three-step analysis for the specific jurisdiction inquiry:

> (1) whether the defendant has minimum contacts with the forum state, i.e., whether it purposely directed its activities toward the forum state or purposefully

> availed itself of the privileges of conducting activities there; (2) whether the plaintiff's cause of action arises out of or results from the defendant's forum-related contacts; and (3) whether the exercise of personal jurisdiction is fair and reasonable.

Id. If the plaintiff can successfully establish the first two prongs, then the burden shifts to the defendant to show that exercising jurisdiction would be unfair or unreasonable. Id.

Under the first prong, "a defendant does not have minimum contacts with a state when it does not have a physical presence in the state; it did not conduct business in the state; and the contract underlying the business transaction at issue in the lawsuit was not signed in the state and did not call for performance in the state." Id. Elaborating further, the Supreme Court has recently identified two important aspects of the relationship between forum State and defendant. "First, the relationship must arise out of the contacts that the 'defendant *himself*' creates with the forum State." Walden 134 S.Ct. at 1122 (quoting Burger King Corp. v. Rudzewicz, 471 U.S. 462, 475 (1985)). Thus, a mere showing of the plaintiff's contacts with the forum State will not suffice. See id. Second, the "minimum contacts" analysis "looks to the defendant's contacts with the forum State itself, not the defendant's contacts with persons who reside there." Id. The plaintiff cannot be the only link between the defendant and the forum. "Rather, it is the defendant's conduct

that must form the necessary connection with the forum State that is the basis for jurisdiction over him." Id.

With the legal framework in place, the Court turns to the plaintiff's complaint.

B.

The plaintiff names seven defendants in her complaint: Janssen Pharmaceuticals, Inc.; Janssen Ortho, LLC; Janssen Research & Development, LLC; Johnson & Johnson Services, Inc.; Johnson & Johnson; Mitsubishi Tanabe Pharma Corporation (Mitsubishi Japan); and Mitsubishi Tanabe Pharma Development America, Inc. (Mitsubishi America). Throughout her 45-page complaint, the plaintiff rarely distinguishes between the defendants, although she acknowledges that they played different roles in the development and distribution of Invokana. As with a Rule 12(b)(6) motion, the Court "accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." See Martin K. Eby Constr. Co. v. Dall. Area Rapid Transit, 369 F.3d 464 (5th Cir. 2004)(internal quotations omitted). The Court does not, however, extend the presumption of truth to mere conclusory allegations. See Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc., 677 F.2d 1045, 1050 (5th Cir. 1982)). Thus, the Court examines the specific assertions the plaintiff makes about each of the Mitsubishi Defendants.

1.

The plaintiff asserts that Mitsubishi Japan is a Japanese pharmaceutical company headquartered in Osaka, Japan. She alleges that Mitsubishi Japan collaborated with Johnson & Johnson to design and develop Invokana. The plaintiff contends that, through its subsidiary, Mitsubishi Japan "is involved in the licensing agreements for pharmaceuticals and drug therapies including Invokana." Finally, she submits:

> Upon information belief, [Mitsubishi Japan], expected or should have expected its acts to have consequences within the United States of America and the State of Louisiana, and by entering into a licensing agreement with Janssen Pharmaceuticals understood that its actions and business practices would subject it to personal jurisdiction in the United States and the State of Louisiana.

Aside from her speculative conclusion that Mitsubishi Japan "should have expected" to be subject to personal jurisdiction in Louisiana by "entering into a licensing agreement with Janssen," the complaint is entirely devoid of facts linking Mitsubishi Japan to Louisiana. Notably absent are allegations that Mitsubishi Japan has any presence in the State, that it conducted any business in the State, or that the licensing agreement was signed in the State. Even more glaring, the plaintiff explicitly states that Mitsubishi Japan's only contact with Louisiana is *through* its subsidiary, Mitsubishi America, or through Janssen Pharmaceuticals. The Court is reminded that personal jurisdiction only "arise[s] out of the

contacts that the defendant *himself* creates with the forum State." Walden 134 S.Ct. at 1122 (internal quotations omitted). The plaintiff has fallen well-short of making a prima facie showing of personal jurisdiction over Mitsubishi Japan.

2.

The plaintiff asserts even less about Mitsubishi America. She claims that Mitsubishi America is a subsidiary of Mitsubishi Japan headquartered in New Jersey. She adds that Mitsubishi America "licenses pharmaceuticals and drug therapies including Invokana for its parent corporation [Mitsubishi Japan]." Her only other allegation is that Mitsubishi America "has transacted and conducted business within the State of Louisiana." Construing these facts as true, the plaintiff has not asserted the minimum contacts necessary to establish personal jurisdiction.

Fatally, the plaintiff fails to make any link between Mitsubishi America's alleged contacts with Louisiana and her damage claims. The jurisdictional inquiry is whether the defendant's *suit-related* conduct creates a substantial connection with Louisiana. See Walden, 134 S.Ct. at 1121. That Mitsubishi America "licenses pharmaceuticals" for its parent company does not establish that it "purposely directed its activities toward the forum state or purposefully availed itself of the privileges of conducting activities there." Monkton, 768 F.3d at 433. The plaintiff has now had two opportunities to assert facts sufficient

to establish personal jurisdiction over the Mitsubishi Defendants. Twice she has failed.

Accordingly, the plaintiffs' claims against the Mitsubishi Defendants are dismissed with prejudice.[3]

II. The Janssen Defendants

The Janssen Defendants move to dismiss the plaintiff's amended complaint under Federal Rule of Civil Procedure 12(b)(6).

Rule 12(b)(6) allows a party to move for dismissal of a complaint for failure to state a claim upon which relief can be granted. Under Rule 8(a)(2) of the Federal Rules of Civil Procedure, a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Ashcroft v. Iqbal, 556 U.S. 662, 678-79 (2009) (citing Fed. R. Civ. Proc. 8). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Id. at 678 (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

[3] The plaintiff's request for limited jurisdictional discovery is denied. The Court notes that the plaintiff has all but admitted her service upon Mitsubishi Japan was insufficient. It appears that, after a months-long opportunity to effect proper service, the plaintiff has yet to do so. The Court finds that limited jurisdictional discovery on these circumstances is not in the interests of justice.

Thus, in considering a Rule 12(b)(6) motion, the Court "accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" See Martin K. Eby Constr. Co. v. Dall. Area Rapid Transit, 369 F.3d 464 (5th Cir. 2004) (quoting Jones v. Greninger, 188 F.3d 322, 324 (5th Cir. 1999)). But, in deciding whether dismissal is warranted, the Court will not accept conclusory allegations in the complaint as true. Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc., 677 F.2d 1045, 1050 (5th Cir. 1982)). Indeed, the Court must first identify allegations that are conclusory and thus not entitled to the assumption of truth. Iqbal, 556 U.S. at 678-79. A corollary: legal conclusions "must be supported by factual allegations." Id. at 678. Assuming the veracity of the well-pleaded factual allegations, the Court must then determine "whether they plausibly give rise to an entitlement to relief." Id. at 679.

"Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Twombly, 550 U.S. at 555 (citations and footnote omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the

line between possibility and plausibility of entitlement to relief." Id. at 678 (internal quotations omitted) (citing Twombly, 550 U.S. at 557). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief'" thus "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (alteration in original) (citation omitted). Simply stated, Twombly is a direct rejection of boilerplate.

The Janssen Defendants submit that all of the plaintiff's claims are insufficiently pled under the Twombly-Iqbal standard. And they add that the plaintiff's defective design claim is preempted by federal law. Finally, they urge that all of the plaintiff's claims against Janssen Ortho LLC, Johnson & Johnson Services, Inc., and Johnson & Johnson are also preempted by federal law. The Court considers each separately.

A. The Louisiana Products Liability Act

The LPLA provides "the exclusive theories of liability for manufacturers for damage caused by their products." La. R.S. § 9:2800.52. The LPLA only allows recovery if a product is "unreasonably dangerous." A product can only be unreasonably dangerous in four exclusive ways: 1) in construction or composition; 2) in design; 3) because of an inadequate warning; or 4) because it does not conform to an express warranty. La. R.S. § 9:2800.54. The characteristic that makes the product unreasonably

dangerous must exist at the time the product left control of the manufacturer. Id.

1. Defect in Construction or Composition

A claim for defect in construction or composition arises when a product is defective "due to a mistake in the manufacturing process." Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 263 (5th Cir. 2002). This is a narrow and demanding test. The plaintiff must prove that, at the time the product left the manufacturer's control, it deviated materially from the manufacturer's specifications or performance standards for the product or from otherwise identical products manufactured by the same manufacturer. La. R.S. § 9:2800.55.

As in her original complaint, none of the facts alleged in the plaintiff's amended complaint suggest that the Invokana she took deviated from the specifications or intended design of the drug. The only substantive allegation to support her defective composition claim is that Invokana deviated from performance standards and other identical products because "it caused dehydration and osmatic diuresis which caused the Plaintiff's kidneys to overwork and eventually fail." But in the next sentence, the plaintiff states, "Other diabetic medications such as metformin or glipizide do not cause the kidneys to over function, leading to kidney failure." The plaintiff demonstrates a

fundamental misunderstanding of the facts required to establish a defect in construction or composition claim.

A defect in construction or composition under the LPLA means that the *particular* product used by the plaintiff deviated from its intended design. The plaintiff must show that the specific Invokana medication that she took was flawed or defective when compared to other Invokana medication; that there was a mistake in the manufacturing process of the specific pills that she ingested. La. R.S. § 2800.55. Nowhere in her amended complaint does she make any such assertion. Her contrast of Invokana to other kinds of diabetes medication is irrelevant to a defective construction or composition claim. Thus, the claim is dismissed with prejudice.

2. Defective Design

Under the LPLA, a product's design is unreasonably dangerous if the plaintiff demonstrates that, at the time the product left the manufacturer's control, "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage and that the danger of the damage outweighed the burden on the manufacturer of adopting the alternative design." Watson v. Bayer Healthcare Pharmaceuticals, Inc., 2013 WL 1558328, 13-212 (E.D. La. April 11, 2013)(Feldman, J.) (quoting La. R.S. § 9:2800.56)(citations omitted). The LPLA "does not allow a fact finder to presume an unreasonably dangerous design solely from the

fact that injury occurred." McCarthy v. Danek Medical, Inc., 65 F. Supp. 2d 410, 412 (E.D. La. 1999).

In her amended complaint, the plaintiff explains at length her theory of how Invokana is defectively designed. She repeatedly articulates that Invokana's design is defective because the drug overworks the kidneys by blocking reabsorption of glucose and forcing the body to excrete excess glucose through urination. As a result of the added strain to the kidneys, she asserts that Invokana increases the likelihood of acute kidney injury and failure. She further claims that the defective design caused her to suffer from these side effects.

The plaintiff does not offer a specific alternative design that would have prevented her injury. Her general theory, however, is that Invokana could have been designed to put less strain on the kidneys. To support this contention, she points to other diabetes medications that she claims have less severe side effects. The Janssen Defendants correctly point out that the mere fact that alternative medications may have different side effects does not validate the plaintiff's defective design claim. But whether the plaintiff can demonstrate an alternative design that satisfies the test under the LPLA is a question of fact to be assessed upon discovery. Requiring plaintiffs to plead "extremely detailed factual allegations to satisfy each element of a products liability action under the LPLA creates a situation where a manufacturer

will not be held liable for defective products because it has sole possession of the necessary document to ultimately prove the claim." Flagg v. Stryker Corp., 2016 WL 1657969, 14-31169 (April 26, 2016 5th Cir.). On this record, the plaintiff has asserted the minimum level of facts sufficient to surpass the line of possibility and advance her claim into the realm of plausibility.

3. Inadequate Warning

"To successfully maintain a failure-to-warn claim under the LPLA, a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning about this characteristic." Stahl, 283 F.3d at 265-66; see La. R.S. § 9:2800.57.

As with her defective design claim, the plaintiff has supplied plausible facts sufficient to show a potential damage-causing characteristic. She includes medical statistics and research showing an alleged correlation between Invokana and kidney injury or failure. She claims that the defendants intentionally concealed or downplayed the seriousness and likelihood of these adverse side effects. Additionally, she contends that the defendants promoted Invokana to physicians and consumers without adequately disclosing the potential risks. Accepting these allegations as true, the plaintiff has adequately stated a potential damage-causing characteristic.

The plaintiff also contends that the warnings regarding Invokana were inadequate in light of the high risks of taking the drug. The Janssen Defendants respond that they provided multiple warnings of the adverse side effects associated with Invokana. They list several paragraphs in the "Prescribing Information" that address the risks of kidney and renal function. The defendants' contentions, however, raise issues of fact that are not ripe for resolution at the pleading stage. Whether the defendants' warnings were adequate is a question that goes beyond the scope of a motion to dismiss under Rule 12(b)(6). The Court must construe the facts in a light most favorable to the plaintiff. Here, she has sufficiently pled facts to make out a plausible claim for inadequate warning.

4. Breach of Express Warranty

To maintain a breach of express warranty claim under the LPLA, a plaintiff must show: "(1) the manufacturer made an express warranty regarding the product, (2) the plaintiff was induced to use the product because of that warranty, (3) the product failed to conform to that express warranty, and (4) the plaintiff's damage was proximately caused because the express warranty was untrue." Caboni v. General Motors Corp., 278 F.3d 448, 452 (5th Cir. 2002). An "express warranty" is a representation or statement about a product that affirms the product possesses specified

characteristics or qualities. See La. R.S. § 9:2800.53(6). It does not include a general opinion or general praise. See id.

The plaintiff asserts in her amended complaint that the defendants expressly warranted that Invokana had been adequately tested and was safe and effective for diabetes treatment. Throughout her amended complaint, she stresses the intensity of the defendants' marketing campaign to promote Invokana. Courts have held that marketing materials may rise to the level of an express warranty if they make claims as to the product's safety. See Kennedy v. Pfizer, Inc., 2013 WL 4590331, 12-1858 (W.D. La. Aug. 28, 2013)(Hicks, J.); Boutte v. Stryker Biotech, LLC, 67 F. Supp. 3d 732, 738-39 (W.D. La. 2014) (Jackson, J.). Accordingly, the Court construes the marketing materials as potential express warranties.

The plaintiff contends that the marketing materials were false because Invokana was not adequately tested and has dangerous side effects that make it unsafe for treating diabetes. She also maintains that the defendants overstated the efficacy of Invokana and deemphasized its risks. The plaintiff adds that she and her physician relied upon these warranties when deciding to begin treatment with Invokana. Had she known of the severe risks, she claims, she would not have taken the drug. The plaintiff adequately alleges three of the four necessary elements.

The final element for which the plaintiff must provide plausible support is the requirement that the express warranty induced her to use Invokana. The Court can only find two allegations that could potentially satisfy the essential element of inducement. In paragraph 199 of the amended complaint, the plaintiff claims:

> Defendants advertised, labeled, marketed and promoted Invokana, representing the quality to health professionals, Plaintiff, and the public in such a way to induce Invokana's purchase or use, thereby making an express warranty that Invokana would conform to the representations.

This boilerplate statement contains the magic word "induce," but it falls short of stating the plaintiff was exposed to the marketing materials or that *she* was induced by them.

Second, in paragraph 70 of the amended complaint, she asserts:

> Prior to Plaintiff's prescription of Invokana, Plaintiff became aware of the promotional materials described herein. Plaintiff was aware that Defendants would not be able to market Invokana without permissions [sic] from the FDA. Based upon her awareness of Invokana being commercially available and marketed in Louisiana, Plaintiff Guidry assumed that Defendants had received permission from the FDA to sell Invokana and therefore, that Invokana was safe for her use for control of her diabetes.

The Court underscores that the plaintiff only vaguely claims that she "became aware" of the promotional materials. She never specifically states that she was induced by the marketing materials or even directly exposed to them.

The Janssen Defendants correctly identify this deficiency in their motion to dismiss, and the plaintiff's anemic response is, "Plaintiff suggests that she was induced to take Invokana because of an alleged express warranty." The plaintiff must do more than elusively "suggest" essential facts to raise her right to relief above the speculative level. If she had actually been exposed to the promotional materials and she was actually induced by them, she would have said so. Plainly. Directly. Instead, she offers up ambiguity and equivocation. The plaintiff has now failed *twice* to submit a short, plain statement showing she is entitled to relief for breach of express warranty. Her claim is dismissed with prejudice.

5. Redhibition

The LPLA preserves redhibition claims "only to the extent the claimant seeks to recover the value of the product or other economic loss." De Atley v. Victoria's Secret Catalogue, LLC, 2004-0661 (La. App. 4 Cir. 5/14/04); 876 So. 2d 112, 115. "A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." La. C.C. art. 2520. Alternatively, a defect is redhibitory when "without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price." Id.

Because the Court has found that the plaintiff has satisfied the pleading standard to plausibly make out a claim for defect in design and inadequate warning, those alleged defects are doctrinally redhibitory as well. The Court views the facts in a light most favorable to the plaintiff. In her amended complaint, she pleads that she would not have purchased Invokana had she known the extent of the risks of kidney failure or kidney injury. On this record, the plaintiff's claim for redhibition is sufficiently pled.

B. Preemption of Defective Design Claim

The Janssen Defendants submit that the plaintiff's defective design claim is preempted by federal law. A claim for defect in design requires proof that "[t]here existed an alternative design for the product that was capable of preventing the claimant's damage." La. R.S. § 9:2800.56. The Janssen defendants correctly point out that this claim is premised on the contention that the defendants should have designed Invokana *differently.* Federal law, however, prohibits a drug manufacturer from changing the chemical composition of a prescription drug without FDA approval. The Janssen defendants urge that it is impossible for them to change the design of Invokana unilaterally. And because Louisiana tort law imposes a duty that is prohibited by federal law, the Janssen defendants invoke the doctrine of implied conflict preemption.

The Supremacy Clause mandates that the laws and treaties of the United States "shall be the supreme Law of the Land . . . and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. "Accordingly, it has long been settled that state laws that conflict with federal law are 'without effect.'" Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013)(quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981). Even in the absence of an express preemption provision, state law is impliedly preempted where it is impossible for a private party to comply with both state and federal requirements. Id.

In several recent cases, the United States Supreme Court has addressed the issue of conflict preemption in the context of state products liability claims against drug manufacturers. But the exact issue presented here - whether a defect in design claim arising from use of a brand name prescription drug is preempted – has not been squarely resolved by the Supreme Court or by the Fifth Circuit. The Janssen defendants rely on a trilogy of recent Supreme Court decisions to advance their argument that preemption extends to the claims presented here. The Court examines each case.[4]

[4] The Court notes that the Supreme Court was sharply divided in all three cases. Two of them were decided five to four.

1. Wyeth v. Levine

In Wyeth v. Levine, 555 U.S. 555 (2009), the Supreme Court held that a patient's state law claim against a brand name drug manufacturer for inadequate warning of a prescription medication was *not* preempted by federal law. There, the plaintiff received an injection of Phenergan, a brand name drug used to treat nausea. The drug came in contact with the plaintiff's artery causing gangrene to spread throughout her arm. Doctors had to amputate at her right forearm. The plaintiff sued the drug manufacturer claiming that the labeling was defective because it failed to adequately warn of the dangers of injecting the drug.[5] The drug manufacturer responded that the plaintiff's claim was preempted by federal laws and regulations under the Food, Drug, and Cosmetic Act (FDCA).

The drug manufacturer invoked two theories of preemption. First, it argued that it would have been impossible for it to comply with the state law duty to modify Phenergan's warning labels without violating federal law. It claimed that the FDCA prohibited it from unilaterally altering the drug label. Second, it claimed that the state tort action created an unacceptable obstacle to the

[5] Notably, the drug label did warn that "extreme care" should be exercised to avoid "inadvertent intra-arterial injection," due to the likelihood of "gangrene requiring amputation." The plaintiff claimed, however, that the label should have instructed only the IV-drip method of administration.

FDCA because it would substitute a lay jury's decision about drug labeling for the expert judgment of the FDA. The Court rejected both theories.

Addressing the impossibility argument, the Court reasoned that FDA regulations permit, and even require, that drug manufacturers maintain and update their labeling with new safety information as it is acquired. Specifically, the "changes being effected" regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it need not wait for FDA pre-approval. Id. at 568 (citing 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). "Thus, when the risk of gangrene from IV-push injection of Phenergan became apparent, [the manufacturer] had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." Id. at 571. The Court pointed out, however, that the FDA could reject proposed changes to the labeling, but absent clear evidence of the FDA's intent to do so, it was not impossible for the drug manufacturer to comply with both state and federal law. Id. at 571. Notably, the Court recognized that "[i]mpossibility pre-emption is a demanding defense." Id. at 572.

The Court also rejected the manufacturer's contention that state law tort claims interfere with Congress' intent to vest in the FDA the sole power to make drug labeling decisions. Relying on historical context, the Supreme Court concluded that Congress' intent in enacting the FDCA was to supplement state law protections for consumers, not replace them. Accordingly, the Court concluded that a drug label could be inadequate under state tort law, even if it has been previously approved by the FDA.

2. PLIVA, Inc. v. Mensing

Two years later, in PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), the Supreme Court held that federal drug regulations applicable to generic drug manufacturers preempt state-law failure-to-warn claims. In two consolidated cases, the plaintiffs were prescribed Reglan, a drug designed to accelerate the movement of food through the digestive system. Both plaintiffs received a generic version of the drug called metoclopramide. After taking the drug for several years, the plaintiffs developed tardive dyskinesia, a severe neurological disorder that is often irreversible.

The plaintiffs sued the generic drug manufacturers under state law for failing to provide adequate warnings of the risk of developing tardive dyskinesia.[6] The manufacturers responded that

[6] The states were Louisiana and Minnesota.

the state law claims were preempted by federal drug regulations. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act in which it permitted streamlined FDA approval for generic drugs. Instead of repeating the arduous process that new drugs must undergo, the law allowed generic drug manufacturers to obtain approval simply by showing that the generic drug is equivalent to an already-approved brand name drug. The generic drug application must "show that the [safety and efficacy] labeling proposed . . . is the same as the labeling approved for the [brand-name] drug." Id. at 612-13 (citing 21 U.S.C. § 355(j)(2)(A)(v)).

"As a result," the Court wrote, "brand-name and generic drug manufacturers have different federal drug labeling duties." Id. at 613. Brand-name manufacturers are responsible for the accuracy and adequacy of their labels, while generic drug manufacturers are responsible for ensuring their warning labels are the same as the brand name's. The Court reasoned that state law had imposed a duty on the drug manufacturers to attach safer labels to their generic drugs. Federal law, however, demanded that generic drug labels be the same as the corresponding brand-name drug labels. "It was not lawful under federal law for the Manufacturers to do what state law required of them." Id. at 618. The Court concluded that "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to

keep the label the same." Id. Under these circumstances, state law was preempted.

3. Mutual Pharmaceutical Co. v. Bartlett

Another two years later, in Mutual Pharmaceutical Co. v. Bartlett, 133 S. Ct. 2466 (2013), the Supreme Court held that a plaintiff's state law design defect claim against the manufacturer of a generic drug was preempted by federal law. There, the plaintiff was prescribed Clinoril, a nonsteroidal anti-inflammatory drug (NSAID), for shoulder pain. She received a generic form of the drug called sulindac. Shortly after she consumed the drug, the plaintiff developed an acute case of toxic epidermal necrolysis, a horrendous disease that caused sixty to sixty-five percent of the plaintiff's skin to either burn off or turn into an open wound. The plaintiff was left severely disfigured and nearly blind.

The plaintiff succeeded on her design defect claim against the generic drug manufacturer at trial. New Hampshire law requires manufacturers to ensure that the products they design, manufacture, and sell are not "unreasonably dangerous." Id. at 2474. The Court found that this duty could be satisfied by either changing the drug's design or by changing its labeling. Relying on Mensing, the Court reasoned that a generic drug manufacturer is prohibited by federal regulations from doing either.

A redesign of the drug was impossible because "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based." Id. at 2475 (citing 21 U.S.C. §§ 355(j)(2)(A)(ii)-(v) and (8)(B)). If the manufacturer were to change the composition of the generic drug, "the altered chemical would be a new drug that would require its own NDA [New Drug Application] to be marketed in interstate commerce." Id. Thus, under New Hampshire law, the only way for the generic drug manufacturer to satisfy its duty not to sell an "unreasonably dangerous" drug, was to strengthen the warning labels. But because federal law, as interpreted in Mensing, prohibits a generic drug manufacturer from changing the label, state law imposed a duty to violate federal law. As in Mensing, the plaintiff's tort claim was preempted.

Here, the Court emphasizes a critical distinction between Levine on the one hand and Mensing and Bartlett on the other. Levine dealt with preemption of state law claims against a *brand name* drug manufacturer; Mensing and Bartlett concerned preemption as applied to *generic* drug manufacturers. The difference is paramount.

Unequivocally, the Supreme Court in Mensing and Bartlett held that state law inadequate warning and design defect claims against *generic* drug manufacturers are preempted. The reasoning is clear:

federal law requires a generic drug to have identical labeling and ingredients as its brand name counterpart. Generic drug manufacturers do not design new drugs; they copy existing ones. As such, a generic drug manufacturer simply cannot comply with its state law duty to alter the generic drug's chemical composition or strengthen its labeling without violating the federal requirement that the generic version be identical to the brand name. Preemption in the *generic* drug context is decided.

The facts presented here are more closely parallel to Levine. In Levine, the Supreme Court considered whether a state law inadequate warning claim against a *brand name* drug manufacturer was preempted. The Court answered no. Unlike *generic* drug manufacturers, brand name drug manufacturers *do* control (at least to some extent) the strength of their labeling and the chemical composition of the drug. Thus, the preemption analysis in the context of brand name drugs differs entirely from that of generic drugs. Like Levine, the plaintiff here asserts claims against a brand name drug manufacturer. But whereas Levine presented the question of whether an *inadequate warning* claim against a brand name drug manufacturer was preempted, the different question posed here is whether a *defective design* claim against a brand name drug manufacturer is preempted. This is a new and undecided issue in this Circuit.

The Sixth Circuit is the only appellate court that has squarely addressed the issue presented here. The Court looks to that Circuit for guidance.

4. Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.

In Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc. 808 F.3d 281 (6th Cir. 2015), the Sixth Circuit held that the plaintiff's state law defective design claim against a brand-name drug manufacturer was preempted by federal drug regulations. There, the young female plaintiff had a stroke after using the birth control patch, ORTHO EVRA®. New York law provides that a product is defectively designed if it "was not reasonably safe because there was a substantial likelihood of harm and it was feasible to design the product in a safer manner." Id. at 297 (quoting Doomes v. Best Transit Corp., 17 N.Y. 3d 594, 608 (2011)).

The plaintiff advocated two theories for her defective design claim. First, she claimed that the drug manufacturer had a duty to change the design of ORTHO EVRA once it discovered it was unreasonably dangerous after FDA approval. The Sixth Circuit dismissed this claim as "clearly preempted by federal law." Id. at 298. The court reasoned that, once a brand-name (or generic) drug is federally approved, "the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'" Id.

(quoting 21 C.F.R. § 314.70(b)(2)(i)). Changing the dosage level or any active ingredient, the court found, constituted a "major change." The court concluded that it was impossible for the manufacturer to change the composition of the drug after it was approved by the FDA. Thus, the plaintiff's claim was preempted.

The plaintiff's second theory was that no federal law prevented the defendants from designing a safer drug *before* FDA approval. She claimed that the existence of the contraceptive Evra, which was chemically distinct from ORTHO EVRA® and was marketed in Canada and Europe, showed that a better, alternative design was possible before seeking FDA approval. The Sixth Circuit rejected this argument as "too attenuated." The court reasoned:

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed ORTHO EVRA® differently, the FDA would have approved the alternative design. Next, we would have to assume that Yates would have selected this method of birth control. Further yet, we would have to suppose that this alternate design would not have caused Yates to suffer a stroke. This is several steps too far.

The Sixth Circuit compared the plaintiff's pre-approval theory to a claim that the Supreme Court had already rejected. In Mensing, the plaintiffs argued that the generic drug manufacturers should have asked the FDA for help in changing the corresponding brand name label so that they could then change the generic drug label to make it safer. The Supreme Court rejected this argument in Mensing, reasoning:

> The Manufacturers "freely concede" that they could have asked the FDA for help. If they had done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide.

Mensing, 564 U.S. at 619. The Sixth Circuit concluded that the defendants "could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing ORTHO EVRA®, and certainly prior to Yate's use of the drug." Id. at 300.

The Sixth Circuit identified one more reason why it rejected the pre-approval theory. In Bartlett, the Supreme Court dismissed the First Circuit's solution that the generic drug manufacturer could have simply stopped selling the drug to comply with both state and federal law. The Sixth Circuit reasoned that, essentially, the plaintiff was asking for the same solution: "In contending that defendants' pre-approval duty would have resulted in a birth control patch with a different formulation, Yates essentially argues that defendants should never have sold the FDA-approved formulation of ORTHO EVRA® in the first place." Id. The Sixth Circuit rejected this "never-start selling" rationale for the same reasons the Supreme Court rejected the "stop-selling" rationale in Bartlett.

5. Preemption of the LPLA

As instructed by the Supreme Court, this Court begins with recognition of the "two cornerstones" of preemption jurisprudence. Levine, 555 U.S. at 565. "First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, [i]n all pre-emption cases, and particularly in those in which Congress has legislated . . . in a field which the States have traditionally occupied . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Id. (internal quotations omitted).

To determine whether a conflict exists between the LPLA and federal drug regulations, the Court must first identify the requirements of state law. Under the LPLA, a product is unreasonably dangerous in design if, at the time the product left the manufacturer's control:

> (1) There existed an alternative design for the product that was capable of preventing the claimant's damage; and
>
> (2) The likelihood that the product's design would cause the claimant's damage and the gravity of that damage outweighed the burden on the manufacturer of adopting such alternative design and the adverse effect, if any, of such alternative design on the utility of the product.

La. R.S. § 9:2800.56.

First, the Court draws a distinction between a defect in design claim and an inadequate warning claim. The LPLA clearly

separates the two claims; this Court does the same. In the prescription drug context, showing that a drug's warning label was inadequate does not support a claim for defective design. Rather, it supports a separate claim for inadequate warning. As a result, under Louisiana law, to show that a prescription drug is defective in design, one must show that there existed a safer, alternative chemical composition.[7]

As such, the Court agrees with the Sixth Circuit in Yates that, to the extent the plaintiff contends that the defendants should have adopted a new design for Invokana *after* it was approved by the FDA, her defective design claim is preempted. As the Supreme Court recognized in Bartlett, "Once a drug – whether generic or brand-name – is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" Bartlett, 133 S.Ct. at 2471 (quoting 21 C.F.R. § 314.70(b)(2)(i)). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." Mensing, 564 U.S. at 620. "[W]hen a party cannot satisfy

[7] This is supported by the Supreme Court's finding in Bartlett that the only two ways a drug manufacturer could ensure its product was not "unreasonably dangerous" was to change the drug's chemical composition or its labeling. In that case, the Court applied New Hampshire law, which, unlike Louisiana law, does not draw a clear distinction between defect in design and inadequate warning.

its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." Id. at 623-24.

Here, the defendants could not have independently adopted an alternative design for Invokana after the FDA approved the drug. Once Invokana was approved, federal drug regulations prohibit the defendants from altering its chemical composition. Any state requirement that a brand name drug manufacturer should have adopted an alternative design to a prescription drug after it was approved by the FDA is preempted.

The remaining question is narrow: Is the plaintiff's defective design claim against a brand name drug manufacturer preempted, even on a theory that the manufacturer should have adopted a safer, alternative design *before* seeking FDA approval of the drug? The answer is not obvious.

The Court first notes that, if it finds the plaintiff's defective design claim is preempted, even under a pre-FDA approval theory, the result is that a Louisiana plaintiff can *never* bring a defective design claim against a drug manufacturer.[8] Critically,

[8] The Supreme Court already held in Bartlett that defective design claims against *generic* drug manufacturers are preempted. If this Court holds the same in the *brand name* drug context, then

the LPLA "establishes the *exclusive* theories of liability for manufacturers for damage caused by their products." La. R.S. § 9:2800:52 (emphasis added). No other state law remedy against a drug manufacturer is available. And no federal remedy exists either:

> Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.

Levine, 555 U.S. at 574. As a result, if the defendants' preemption argument prevails, Louisiana plaintiffs will have no remedy against a drug manufacturer for a defect in a drug's design.

Inescapably, the Court faces fundamental public policy questions. Foremost, did Congress intend the FDA to be judge and jury in deciding whether a brand name drug is safe and effective? Or can a plaintiff attempt to show that a drug's design was unreasonably dangerous, even though the FDA approved it? Asked differently: Are drug manufacturers shielded from liability if their drug causes harm due to a defect in design simply because the FDA said the drug was safe? The Supreme Court has offered some guidance.

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effectively, all defective design claims against drug manufacturers under Louisiana law are preempted.

In Levine, the Supreme Court explicitly rejected the drug manufacturer's contention that "the FDCA establishes both a floor and a ceiling for drug regulation." Levine, 555 U.S. at 573-74. Rather, the Court found that "all evidence of Congress' purposes is to the contrary." Id. at 574. The Court rejected the theory that the plaintiff's inadequate warning claim created an "unacceptable obstacle" to the accomplishment of the full purposes of FDCA: "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." Id. "Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." Id. at 575. The Court observed, "As it enlarged the FDA's powers to protect the public health and assure the safety, effectiveness, and reliability of drugs, Congress took care to preserve state law." Id. at 567 (internal quotations and citations omitted). Further, the Court pointed out, "The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a 'direct and positive conflict' with the FDCA." Id. (citations omitted). The Supreme Court in Levine concluded that a drug label may be inadequate under state tort law, even if it has been

approved by the FDA. This is strong evidence that the FDA is not the be-all-end-all in drug regulations.

The defendants urge, however, that preemption applies specifically to Louisiana design defect claims because of the way the state statute is written. At oral argument, defense counsel suggested that a pre-FDA approval design defect claim does not exist under Louisiana law because the relevant question is whether the product was unreasonably dangerous "at the time it left the manufacturer's control." See La. R.S. § 9:2800.56. It is undisputed that prescription drugs cannot be sold to the public until after FDA approval. And because the drug "leaves the manufacturer's control" when the drug is sold to consumers, say the defendants, the "unreasonably dangerous" analysis always occurs post-FDA-approval. But this argument unravels the defendants' entire preemption theory. Defective design claims are supposedly preempted because the drug manufacturer loses control to alter the chemical composition of the drug *once the FDA approves it.* Application of the defendants' preemption theory necessarily entails that the drug "leaves the manufacturer's control" when the FDA approves it, not when it is sold to consumers. Consequently, the "unreasonably dangerous" analysis in the defective design context necessarily occurs pre-FDA approval (the only period in which the drug manufacturer has control over the drug's design).

The defendants fall back on the Supreme Court's explicit language in Mensing: "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." Mensing, 564 U.S. at 620. It is true that the defendants cannot independently sell pharmaceutical drugs without FDA approval. It is also true that, once a prescription drug is approved by the FDA, the defendants cannot independently change the chemical composition of the drug without special permission from the FDA (or essentially creating a new drug). But the dispositive question presented here is simply: Can a drug manufacturer independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval? The answer is yes.

This Court is unpersuaded by that part of the Sixth Circuit's reasoning in Yates concerning preemption in the pre-FDA approval context. The Sixth Circuit held a pre-approval duty was "too attenuated," reasoning:

> To imagine such a pre-approval duty exists, we would have to speculate that had defendants designed ORTHO EVRA® differently, the FDA would have approved the alternative design. Next, we would have to assume that Yates would have selected this method of birth control. Further yet, we would have to suppose that this alternate design would not have caused Yates to suffer a stroke. This is several steps too far.

But the Sixth Circuit merely outlines the requisite assumptions for *all* defective design claims under the LPLA. Indeed, every

defective design claim requires consideration of hypothetical scenarios – what different steps *could have* been taken that *may have* prevented the plaintiff's injury. The only added assumption in the pharmaceutical context is that the FDA would have approved the safer, hypothetical drug. It is not too attenuated to assume that the FDA would approve a safer, alternative design of a drug that it has already approved. Nor does the Court share the Sixth Circuit's reservations about the so-called "never-start-selling" argument. Indeed, the raison d'être of products liability litigation is to penalize manufacturers who design unreasonably dangerous products *in hopes that they never start selling them*. State products liability law functions as a compliment to federal drug regulations to keep unreasonably dangerous drugs off the market.

"Impossibility pre-emption is a demanding defense." Levine, 555 U.S. at 573. The Court must assume "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Id. at 565. Nowhere has Congress clearly manifested its intent to supersede state tort law by federal drug regulations. To the contrary, as the Supreme Court notes, "powerful evidence" supports the opposite conclusion. See Levine, 555 U.S. at 575.

Here, the plaintiff states in her complaint that the defendants knew Invokana's design posed an unreasonably dangerous

risk of kidney injury before it was approved by the FDA, yet they sought FDA approval nonetheless.[9] Louisiana law imposes a duty on all manufacturers to consider feasible, alternative designs and reasonably weigh the risks and utility of the final product before it leaves the manufacturer's control. Federal law does not prevent a drug manufacturer from complying with this state-imposed duty before seeking FDA approval. Far from impossible, the two are complimentary, preferable, and perhaps necessary to protect the public health and assure the safety, effectiveness, and reliability of drugs. See Levine, 555 U.S. at 567.

Accordingly, the Court finds that in the narrow, pre-FDA approval context, the plaintiff's defective design claim is not preempted by federal drug law.

C. Preemption of Johnson & Johnson and Ortho Defendants

Finally, the Janssen Defendants contend that all of the plaintiff's claims against Johnson & Johnson Services, Inc., Johnson and Johnson, and Janssen Ortho, LLC are preempted by federal law. This argument is flawed for the same reasons discussed above.

[9] While it may be a tall order to prove facts necessary to show that the FDA approved a drug that was unreasonably dangerous under Louisiana law, the Court must construe the well-pled facts in favor of the plaintiff at this stage.

The Janssen Defendants submit that federal drug regulations permit only the New Drug Applicant to change a drug's composition or labeling once it is approved by the FDA. The New Drug Applicant may only effect such changes after receiving permission from the FDA. Because Janssen Pharmaceuticals is the only New Drug Applicant, the argument goes, the other defendants are prohibited from changing Invokana's design or labeling after the FDA approved it.

As explained, the plaintiff contends in her amended complaint that the defendants knew that Invokana's design and labeling were unreasonably dangerous *before* seeking FDA approval. This is a question of fact that the Court must presently view in favor of the plaintiff. Here, the plaintiff has *specifically* pled that each of the Janssen Defendants – including the Johnson & Johnson defendants – designed and manufactured Invokana, a fact the Court presumes true. Because state law imposes pre-FDA approval duties on drug manufacturers, and because state law is not preempted in that context, it was arguably possible for the defendants to fulfill those duties before seeking FDA approval.

IT IS ORDERED that the Mitsubishi Defendants' motion is GRANTED. The plaintiff's claims against the Mitsubishi Defendants are DISMISSED WITH PREJUDICE.

IT IS FURTHER ORDERED that the Janssen Defendants' motion is GRANTED IN PART and DENIED IN PART. The plaintiff's defect in

construction or composition and breach of express warranty claims are DISMISSED WITH PREJUDICE. Her claims for defective design, inadequate warning, and redhibition against the Janssen Defendants survive.

New Orleans, Louisiana, August 29, 2016

MARTIN L. C. FELDMAN
UNITED STATES DISTRICT JUDGE